Message Text

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ORIGIN HEW-06

INFO OCT-01 OES-05 ISO-00 ARA-10 AF-06 EUR-12 /040 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: MBEAUBIEN

DHEW/OIH: MACODDING
ARA/CAR:JETHYDEN(INFO)
ARA/CAR:DASTRASSER(INFO)
AF/E:RSBARRETT(INFO)
EUR/NE:SWORREL(INFO)
ARA/CAR:GPALAZZOLO(INFO)

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R 140023Z JAN 76

FM SECSTATE WASHDC

TO AMEMBASSY BRIDGETOWN

AMEMBASSY SANTO DOMINGO

AMEMBASSY ADDIS ABABA

AMEMBASSY NAIROBI

AMCONSUL HAMILTON

AMCONSUL CURACAO

UNCLAS STATE 008737

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BB, DR, ET, KE, BD, NA

SUBJECT: FDA ADVISORY - BACTERIAL CONTAMINATION LIQUID ANTACID

1. FDA ADVISES THAT:

PRODUCT INVOLVED: CREAMALIN ANTACID LIQUID IN 16 FL. OZ. AND 8 FL. OZ. BOTTLES AND WINGEL ANTACID LIQUID IN 12 FL. OZ. AND 6 FL. OZ. BOTTLES WITH BOTH PRODUCTS LABELED IN PART: "XXX WINTHROP LABORATORIES, DIVISION OF STERLING DRUG, INC., NEW YORK, N.Y. 10016 XXX".

LOT NUMBERS: ALL LOT NUMBERS AND SIZES PRESENTLY ON THE

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MARKET AND IN DISTRIBUTION CENTERS. THE FIRM HAS BEEN DISTRIBUTING THE PRODUCTS FOR 25 YEARS. ALL DISTRIBUTION

CEASED DECEMBER 15, 1975.

REASON FOR ADVISORY: BASED ON BACTERIAL ANALYSIS OF THE FIRM'S RETAINED SAMPLES, THE FOLLOWING ORGANISMS WERE IDENTIFIED BY THE NEW YORK DISTRICT OFFICE STATE LABORATORY: CREAMALIN LIQUID - KLEBSIELLA PNEUMONIAE, ENTEROBACTER CLOACAE, ENTEROBACTER AGGLOMERANS, ACHROMOBACTER BIO-TYPE 2, PSEUDOMONAS STUTZERI; WINGEL LIQUID - PSEUDOMONAS AERUGINOSA.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED MAILGRAMS AND/OR LETTERS CONCERNING THE BACTERIAL CONTAMINATION OF THE TWO PRODUCTS AND FIRM'S RECOMMENDATIONS FOR THE DISPOSITION OF THE PRODUCTS. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY SHOULD BE DIRECTED TO THE FIRM, WINTHROP LABORATORIES, DIVISION OF STERLING DRUG INC., NEW YORK, N. Y. 10016.

3. FOREIGN CONSIGNEES AS FOLLOWS:

STERLING DRUG INTERNATIONAL WINGEL
C/O A.S. BRYDEN AND SONS
BARBADOS LTD.
P.O. BOX 403
BRIDGETOWN, BARBADOS, W.I.

KEITH EDWARDS WINGEL

P.O. BOX 238

ST. JOHN'S ANTIGUA, W.I.

GEORGE F. HUGGINS AND CO. WINGEL

(GRENADA) LTD.

GEDDES GRANT DIVISION

P.O. BOX 46 ST. GEORGES GRENADA, W.I.

PETER AND CO., LTD. WINGEL

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P.O. BOX 84 CASTRIES ST. LUCIA, W.I.

COREA AND CO., LTD. WINGEL

P.O. BOX 112

KINGSTOWN, ST. VINCENT, W.I.

STERLING PRODUCTS INT'L., INC. CREAMALIN

APARTADO 1338

SANTO DOMINGO DOMINICAN REPUBLIC

STERLING DRUG INT'L., INC.

WINGEL

P.O. BOX 5675

ADDIS ABABA, ETHIOPIA

STERLING PROD. INT'L., LTD.

WINGEL

P.O. BOX 40942 NAIROBI, KENYA

BERMUDA GENERAL AGENCY

WINGEL

P.O. BOX 506

HAMILTON, BERMUDA

MANRIQUE CAPRILES AND SONS

CREAMALIN

P.O. BOX 143

CURACAO, NETHERLANDS

ANTILLES

ARTURO M. ARENDS

CREAMALIN

P.O. BOX 19

ARUBA, NETHERLANDS ANTILLES KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X Capture Date: 01 JAN 1994 Channel Indicators: n/a

Current Classification: UNCLASSIFIED

Concepts: DRUGS, FOOD CONTAMINATION, RECALLS

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Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:

Document Number: 1976STATE008737
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Drafter: JRWEINROTH, M.D.: AMS

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Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MÁY 2006

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Subject: FDA ADVISORY - BACTERIAL CONTAMINATION LIQUID ANTACID TAGS: OGEN, ETRD, TBIO, BB, DR, ET, KE, BD, NA

To: BRIDGETOWN MULTIPLE

Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006